



Food and Drug Administration
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June 22, 2015

Visco Vision Inc.
% Ms. Jennifer Ting
Jens Medical Consulting Ltd.
6F No 39, Ln 224, Jixian Rd
Luzhou Dist. 247 TW New Taipei City
Taiwan R.O.C

Re: K141348
Trade/Device Name: Visco Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: May 18, 2014
Received: May 22, 2014

Dear Ms. Ting:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

k141348

Device Name

VISCO Soft Contact Lens

Indications for Use (Describe)

The VISCO Soft (Hydrophilic) Contact Lenses is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 2.00D or less where the astigmatism does not interfere with visual acuity. Eyecare practitioners may prescribe the lens for either single-use disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only. The VISCO Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

005_510(K) SUMMARY

Preparation Date: May 29, 2015

5.1 Establishment Information:

Name Visco Vision Inc.
Address 2F, No. 789, Bo-Ai Street, Chubei City, Hsinchu County, 302
Taiwan, R.O.C.
Phone No. 886-3-6205516
Fax No. 886-3-5536268

5.2 Owner:

Company Visco Vision Inc.
Name Ted TT Huang
Address 2F, No. 789, Bo-Ai Street, Chubei City, Hsinchu County, 302
Taiwan, R.O.C.
Phone No. 886-3-6205516
Fax No. 886-3-5536268

5.3 US Agent:

Name Jessica LeeChen
Address 44855 Lafayette Dr. Novi, MI 48377 USA
Phone No (248)380-6686
E-mail jessicaleecheen@yahoo.com

5.4 Contact Person:

Name Jennifer TING
Phone No 886-2-82823192
Fax No 886-2-82867686
e-mail: jen.medical@msa.hinet.net

5.5 Device Identification:

Proprietary Name VISCO Soft Contact Lens
Common Name Soft (hydrophilic) Contact Lenses
Classification Name Lenses, Soft Contact, Daily Wear (21 CFR 886.5925,
Product Code LPL)
Lenses, Soft Contact, Daily Wear (Disposable),
(21 CFR 886.5925, Product Code MVN)
Classification II

5.6 Legally Marketed Equivalent Device:

Predicate Device Name	Biofinity (comfilcon A)
Manufacturer	CooperVision Inc.
510(k) Number	K052560
Product Code	LPL, MVN

5.7 Device Description

- The VISCO Soft Contact Lens is a spherical lens with UV blocker.
- The VISCO Soft Contact Lens is available in hemispherical shell.
- The lens material is a silicon combination hydrogel. It is a copolymer of 1-vinyl-2-pyrrolidinone (NVP) and Siloxane macromer. The water content is 47%.
- The VISCO Soft Contact Lens is light blue tinted with “reactive Blue19” for handling visibility purpose.
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 5% (1.1%) in the UVB range of 280-315nm and less than 50% (9.4%) in the UVA range of 316-380nm.
- The lens is supplied in a sterile state, packaged in a buffered saline solution.

5.8 Indication for Use:

The VISCO Soft (Hydrophilic) Contact Lenses is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 2.00D or less where the astigmatism does not interfere with visual acuity. Eyecare practitioners may prescribe the lens for either single-use disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only. The VISCO Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

5.9 Technological characteristics

The spherical lens design specification:

- Diameter 13.0 mm to 15.0 mm
- Center Thickness 0.08mm @ -3.00D (Varies with Power)
- Base Curve 8.0 mm to 9.2 mm
- Power -20.00D to +20.00D

The physical properties of the lenses are:

- Refractive index: 1.410 (hydrated)
- Light transmittance: > 94%
- Water content: 47% by weight in normal saline
- Oxygen permeability 150×10^{-11}
(cm²/sec)(ml O₂/ml.mmHg) measured at 35°C
(intrinsic Dk-Colormetric method)

5.10 Comparison table:

The characteristic comparison to predicate device is summarized in the following table.

Similarities		
Item	Device	Predicate (K052560)
Product Name	VISCO Soft Contact Lens	BIOFINITY (comfilcon A) Soft Contact Lens
Manufacturer	VISCO Technology	CooperVision Inc.
Intended Use	Myopia, Hyperopia	The same
USAN Name	Olifilcon A	comfilcon A
Material	Silicone Hydrogel	Silicone Hydrogel
Lens Design	Spherical	Spheric, aspheric, toric or multifocal
Classification	Class II,	The same
Type	Group I (low water, nonionic)	The same
Water Content	47 %	48 %
Oxygen Permeability (DK, 35°C)	150 (Fatt method)	128 (Fatt method)
Base Curve Range	8.0~9.2	8.0~9.5
Diameter (mm)	13.0~15.0	13.5~15.0
Center Thickness	Varies with design and power (0.08 mm at -3.00D)	0.05 mm – 0.50 mm
Powers	-20.00D to +20.00D in 0.25 steps	The same
Replacement Schedule	Daily wear or Daily Disposable (Single use)	daily wear
Refractive Index	1.410	1.40
Light Transmittance	94%	> 97%

Method of Manufacture	Cast-Molded	The same
Surface Treatment	No	No
Sterilization	steam	The same
Packaging	Blister pack	The same
Blue handling tint	Yes, reactive Blue19	Yes, Phthalocyanine Blue

Mechanical Strength	Device	Predicate (K052560)	Predicate (K000384)
Product Name	Visco	Biofinity (comfilcon A)	Frequency 55
Tensile strength (Mpa)	0.55 ± 0.06	0.50 ± 0.07	0.66
Modulus (Mpa)	0.59 ± 0.05	0.8 ± 0.1	0.48
Elongation at break (%)	106 ± 5	130 ± 2	179
toughness (J/m^3)	0.26 ± 0.02		0.38
Manufacturing method	Cast Mold	Cast Mold	Cast Mold

5.11 Nonclinical Tests Performed

- 5.11.1** Physiochemical studies were conducted according to ISO 18369 First edition 2006-08-15, Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specifications for the lenses.
- 5.11.2** Toxicology studies report shows that the lenses are non-toxic and biocompatibility result is acceptable in ocular environment.

5.12 Clinical Studies

The clinical performance result proves that the safety and effectiveness of the VISCO soft contact lens is non-inferior to the BIOFINITY (comfilcon A) Soft Contact Lens currently marketed by Cooper Vision Inc.

5.13 Conclusion

Comparison to the predicate device for chemical composition, physical and optical properties, it shows that “VISCO Soft Contact Lens” is as safe, as effective and performs as well as the predicate device.